PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

Registry to Investigate the Efficacy and Safety of VenaBlock VeIn SEaling System for VaRicose Veins in SingApore (RIVIERA)

Principal Investigator (PI):

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PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to assess change in patient's symptoms before and after treatment with Venablock© Vein Sealing System for your varicose veins (i.e. "leaky veins" that cause blood to flow backward in your legs). At the same time, we would like to know patient's satisfaction with the procedure. We hope to learn the effectiveness of the Venablock© Vein Sealing System and its treatment outcomes over a period of 1 year.

You were selected as a possible subject in this study as you have chosen Venablock© Vein Sealing System as your choice of treatment for varicose veins. This study will recruit 30 subjects from Singapore General Hospital.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be asked to complete quality of life questionnaires and pain diary post-procedure. In addition, your participation will allow the study team to assess and collect data from your medical records for the study.

Your participation in the study will last for one year. You will be followed up at the doctor's office for 4 times in the course of the study. The estimated time for each visit will take approximately 30-50 minutes.

Schedule of visits and procedures:

Visit	Timeline	Investigations
0	Surgery Day (Baseline)	Medical history review Quality of Life Questionnaires Pain Diary
1	2 weeks post-op (Routine clinical visit)	Physical Examination Quality of Life Questionnaires Return pain diary Duplex Ultrasound
2	3 months post-op (Routine clinical visit)	Physical Examination Quality of Life Questionnaires Duplex Ultrasound
3	6 months post-op (Study visit)	Physical Examination Quality of Life Questionnaires Duplex Ultrasound
4	12 months post-op (Study visit)	Physical Examination Quality of Life Questionnaires Duplex Ultrasound

Table 1: Follow-up Schedule

Duplex ultrasound is a non-invasive imaging technique to assess the vessels at your legs.

Any individually-identifiable data obtained during the course of this study will be stored and used only for the purposes of this study. These data will not be used for future research.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should:

- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital 6 times (max) and undergo all the procedures that are outlined above.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The Research Study is being conducted to assess changes in patient symptoms before and after treatment and to assess patient satisfaction with the procedure in patients receiving the Venablock© Vein Sealing System as the treatment for varicose veins at SGH. The completion of the questionnaires are not part of standard care.

Although Duplex ultrasound may be part of standard medical care, in this study this/these procedure(s) are being performed for the purposes of the research.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

The possible inconveniences of this study is that of the time taken to complete the questionnaires and diary post-surgery, 2 week post-surgery, 3 months, 6 months and 12 months post-surgery. The questionnaires will take approximately 15-20 minutes to be completed. There is minimal risk for breach of confidentiality

POTENTIAL BENEFITS

There is no additional benefit to you from participation in this Research Study. However, your participation in this research study may add to the medical knowledge about the use of the Venablock© Vein Sealing System and its management in varicose vein.

ALTERNATIVES

If you choose not to take part in the Research Study, you will still undergo the treatment of your varicose vein using the Venablock© Vein Sealing System as per discussed with your doctor. However, your data will not be collected as part of the registry. Questionnaires will not be conducted and follow-up schedule will be decided by your doctor.

COSTS OF PARTICIPATION

If you take part in this study, you will have to pay for the following:

- Standard treatment care as per normal clinical practice. No subsidy is provided for participation in this study. For patients, the cost of treatment will then depend on the choice made by the surgeon-in-charge and yourself.

- Consultation and Duplex ultrasound at 2 weeks.

If you take part in this study, the following will be performed at no charge to you:

- Consultation and Duplex ultrasound at 3, 6 and 12 months.

You will be reimbursed $50.00 for your time, inconvenience and transportation costs at the last follow-up

INCIDENTAL FINDINGS

No “incidental findings” (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study) are anticipated. Hence, no re-identification is anticipated.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, continued clinical care as per clinical indication will be provided. However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the trial substance or research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by Singapore General Hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, the Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singapore General Hospital and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Form(s) are the property of SingHealth. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the following:-

- Principal Investigator, Dr Tang Tjun Yip at 6390 5330
- Study Coordinator, Ms Charyl Yap at 6576 7986

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).
If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Registry to Investigate the Efficacy and Safety of VenaBlock VeIn SEaling System for VaRicose Veins in SingApore (RIVIERA)

Principal Investigator:
Adj Asst Professor TANG Tjun Yip
Consultant Vascular and Endovascular Surgeon
Singapore General Hospital
Level 5; Department of Vascular Surgery
Academia, 20 College Road, Singapore 169856
Tel: (65) 6390 5330

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. Impartial witness is applicable for Clinical Trials regulated by HSA, if necessary. An impartial witness should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). The impartial witness should be independent of the trial.
2. In accordance with section 6(d) of the HBRA and regulation 25 of the HBR Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____
Name of Investigator/ Person obtaining consent Signature Date